NOV 2 4 2004

510(K) Summary

K042960

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	October 25, 2004
Device Trade Name:	MCL 30 Dermablate Er:YAG Laser System
Common Name:	MCL 30 Dermablate
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	DermaStar Er:YAG Laser System
Device Description:	MCL 30 Dermablate Er:YAG Laser System is an Er:YAG laser system, having an articulated arm and handpiece. It is a laser with a wavelength of approximately 2.94 μm. Laser emission activation is by foot switch. Overall weight of the laser is 85 kg, and the size is 970x360x650 cm (HxWxD). Electrical requirement is 230 VAC, 16A, 50-60 Hz, single phase. Smoke evacuation is provided by the evacuator integrated into the handpiece that removes the aerosol, a by-product of laser treatment.
Intended Use:	Intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).
Comparison:	The MCL 30 Dermablate Er:YAG Laser System is substantially equivalent to the DermaStar Er:YAG Laser System, with the same principle of operation, the same wavelength and essentially the same power range as the predicate device for the same indications for uses.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The MCL 30 Dermablate Er:YAG Laser System is another safe and effective device for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Asclepion Laser Technologies GmbH
c/o Mr. George Cho
Senior Vice President, Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K042968
Trade/Device Name: MCL 30 Dermablate Er:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 25, 2004
Received: October 28, 2004

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

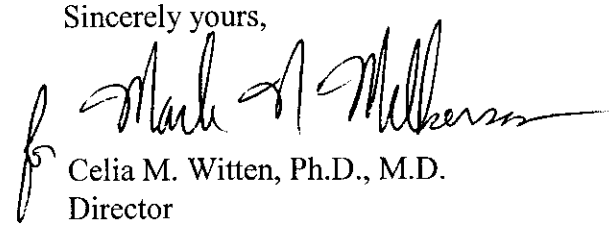
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042968

Device Name: MCL 30 Dermablate Er:YAG Laser System

Indications For Use:

Intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

The smoke evacuator integrated into the handpiece is intended to remove aerosol, a by-product of laser treatment.

Prescription Use ✓ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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